REMARKS

. STATUS OF THE CLAIMS

Claims 1-53 are pending. Claim 1 has been amended to correct a typographical error. No new matter has been added, and support for this amendment can be found throughout the application as filed, for example, in paragraph [0014] on page 8.

Applicants thank the Examiner for indicating that claim 8 would be allowable if rewritten in independent form including all limitations of the base claim and any intervening claims. Office Action at 5. For reasons set forth below, however, all pending claims are patentable over the cited art. Accordingly, Applicants have not rewritten claim 8.

II. <u>ERRORS UNCORRECTED IN THE APPLICATION PUBLICATION</u>

The Office republished this application on January 30, 2003, as Publication No. 2003/0019049 A9. This publication still contains certain errors, for example, in paragraphs [0118], [0162], [0207], [0297], and in claims 17 and 18. These errors were also present in the first publication, Publication No. 2002/0053111 A1.

Applicants wish to state for the record that they <u>do not agree</u> with any erroneous chemical formula found in the application as republished. Furthermore, Applicants disagree with the determination of the Office that the as-filed specification (including the claims) is fuzzy, faint and/or blurred. See Notice of Acceptance of Publication Request dated August 16, 2002. Solely in an effort to minimize expense, Applicants expressly reserve the right to correct these mistakes (if they appear in an issued patent based on this application) under 35 U.S.C. §§ 254 and 255, as they would not constitute new matter or require reexamination.

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II. REJECTION UNDER 35 U.S.C. § 103

Claims 1-53¹ are rejected under 35 U.S.C. § 103(a) as obvious over U.S. Pat. No. 5,993,491 to Lim et al., ("Lim") in view of U.S. Pat. No. 4,842,849 to Grollier et al. ("Grollier") and WO 99/17722 to De La Mettrie et al. ("De La Mettrie"). Applicants disagree with the rejection, as the Examiner has failed to present a prima facie case of obviousness.

The presently rejected claims recite a composition for the oxidation dyeing of keratinous fibers comprising, in a medium suitable for dyeing, at least one oxidation dye precursor chosen from 1-(4-aminophenyl) pyrrolidine compounds of formula (I) and at least one cationic polymer chosen from specific categories as recited in, e.g., claim 1. According to the Examiner, "Lim teaches a hair dyeing comprising 1-(4-aminophenyl) pyrrolidine compounds having formulae similar to the claimed formula." Office Action at 2. Furthermore, the Examiner alleges that Lim teaches a method of dyeing hair as well as a dyeing composition in the form of a kit. The Examiner admits that "[t]he instant claims differ from the reference by reciting a hair dyeing composition comprising dyeing ingredients such as cationic polymers, amine-containing silicones, enzymes as oxidizing agents and direct dyes." *Id.* at 3.

The Examiner attempts to overcome the deficiencies of Lim by resorting to Grollier and De La Mettrie. In part, the Examiner alleges: "The composition [of Grollier] comprises quaternary ammonium polymers such as cationic cyclic polymer ... and] poly

¹ Applicants respectfully point out that, in light of the Examiner's indication that claim 8 would be allowable, this rejection ought to be only of claims 1-7 and 9-53. Regardless, all pending claims are patentable over the cited art.

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quaternary ammonium compounds." *Id.* With respect to De La Mettrie, the Examiner alleges that the reference teaches "a hair dyeing composition comprising amino silicone compounds such as cationic silicone polymers . . ., cationic silicone polymers . . ., enzyme of 2-electron oxidoredouctase . . ., and direct dyes." *Id.* at 4.

The Examiner concludes that a person of ordinary skill in the art would have been motivated to combine Lim, Grollier, and De La Mettrie with a reasonable expectation of success of deriving Applicants' invention. He reasons that the modification of Lim with the polymers, enzymatic oxidizing agents, and direct dyes of the secondary references would have been obvious because "one would expect that the use of quaternary ammonium polymers and amino silicone compounds as conditioning agents with oxidizing enzymes and direct dyes as taught by Grollier and De La Mettrie would be similarly useful and applicable to the analogous composition taught by Lim."

Id. at 4. Applicants disagree.

A. The Examiner Has Not Met the Requisite Evidentiary Burden for Establishing a Prima Facie Case of Obviousness

The standards for proving a prima facie case of obviousness are high. Alleging obviousness based on supposed similar utility and applicability is simply insufficient. Indeed, M.P.E.P. § 2142 states: "The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness." *Cf. In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988). The Federal Circuit, moreover, has required that the record contain "substantial evidence" to support the determination of prima facie obviousness. *In re Zurko*, 258 F.3d 1379, 1386 (Fed. Cir. 2001).

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Specifically, unless "substantial evidence" found in the record supports the factual determinations central to the issue of patentability, the rejection is improper and should be withdrawn. *Id.* In *Zurko*, the Federal Circuit specifically rejected the PTO's reliance on "basic knowledge" and "common sense" to support an obviousness determination when the "assessment of basic knowledge and common sense was not based on any evidence in the record and, therefore, lacks substantial evidential support." *Id.* at 1385. In this case, the Examiner has similarly asserted, without substantial evidentiary support, that a person of ordinary skill in the art would have been motivated to combine Lim, Grollier, and De La Mettrie with a reasonable expectation of success. Such unsubstantiated assertions do not meet the required quantum of evidence.

The Federal Circuit, furthermore, has reaffirmed the Examiner's high burden to set forth a prima facie case of obviousness. Indeed, the Court held that "[t]he factual inquiry whether to combine references must be thorough and searching. It must be based on objective evidence in the record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with." *In re Lee*, 277 F.3d 1338, 1343 (Fed. Cir. 2002). Consistent with *Zurko*, the Court further held that "[t]he examiner's conclusory statements ... do not adequately address the issue of a motivation to combine. This factual question is material to patentability, and could not be resolved on subjective belief and unknown authority." *Id.* at 1343-44.

In this case, too, the Examiner has not presented objective evidence to support the subjective, unsupported assertion of prima facie obviousness. Clearly, if the Examiner desires to further maintain the obviousness rejection over Lim, Grollier, and

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De La Mettrie, the burden is on him to produce evidence. Simply stating "one would expect that the use of quaternary ammonium polymers and amino silicone compounds as conditioning agents with oxidizing enzymes and direct dyes as taught by Grollier and De La Mettrie would be similarly useful and applicable to the analogous composition taught by Lim" does not suffice. Office Action at 4.

B. The Examiner Has Not Shown Any Motivation to Combine the References

Assuming, *arguendo*, the amount of evidence presented by the Examiner would suffice (which, Applicants emphasize, is <u>not</u> true), he still has not proven all the elements of a prima facie case of obviousness. With respect to obviousness in general, the Federal Circuit has admonished:

Measuring a claimed invention against the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field.... [T]he best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement[s] for [a prima facie case of obviousness].

In re Dembiczak, 175 F.3d 994, 999 (Fed. Cir. 1999). Applicants remind the Examiner that he must keep in mind the Court's admonition against hindsight analysis while substantiating the present (or any other) obviousness rejection.

Applicants note that the M.P.E.P. sets forth the requirements for a prima facie case of obviousness:

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the

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art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

M.P.E.P. § 2142 (emphasis added). In this case, the Examiner has failed to present substantial evidence on at least the first two criteria set forth above. The Examiner's burden for showing motivation to combine in the present case requires explicit factual findings regarding a motivation to combine Lim, Grollier, and De La Mettrie. These factual findings must be "clear and particular." *Dembiczak*, 175 F.3d at 999. The Examiner has provided no such evidence here.

Indeed, the references, taken either individually or together, do not objectively teach or even remotely suggest a motivation to combine their teachings. The primary reference, Lim, teaches compositions including primary dye intermediates, such as 1-(4-aminophenyl)-2-pyrrolidinemethanol compounds. Lim, col. 3, lines 1-4. Lim describes these compositions as "offer[ing] a wide range of varying color tints depending upon type and composition of colorant constituents." *Id.* at col. 10, lines 56-58. Lim further praises the advantages of these compositions: "The superior coloring properties of the hair dyeing compositions of the present invention are further evidenced by allowing grayed hair that has not been subjected to prior chemical damage to be covered without problems and with a depth and covering strength that, prior to the discovery of the primary intermediates of the present invention, had only been attained using [a conventional dye intermediate]." *Id.* at col. 10, lines 60-67. Furthermore, the problem solved by Lim is the search "for p-phenylenediamine alternatives possessing better allergenic profiles than p-phenylenediamine." *Id.* at col. 1, lines 58-60. Having read

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Lim's glowing reports of his invention's advantages, a person of ordinary skill in the art would hardly have attempted to improve on his compositions' allegedly superior properties.

Even though Lim does mention that its composition "may include a typical anionic, cationic, nonionic, or amphoteric surfactant," *id.* at col. 9, lines 20-21, this general statement would not have suggested or motivated an ordinarily-skilled artisan to add to the disclosed dye intermediates of Lim the specific cationic polymers recited in the present claims to improve any dyeing properties disclosed in Lim. See M.P.E.P § 2141.02 ("A prior art reference must be considered in its entirety, i.e., as a <u>whole</u>, including portions that would lead away from the claimed invention."); *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000).

Just as Lim does not teach or suggest a motivation to combine, such a teaching is also lacking in Grollier and De La Mettrie. Applicants initially note that Grollier, unlike Lim, concerns problems relating to conditioning hair, for example, "comb-out" and "softness to the touch." *See, e.g.,* Grollier, col. 1, lines 28-59. These problems are solved, as Grollier teaches, through the use of an anionic polymer having vinylsulphonic units in combination with a cationic polymer. Grollier, col. 1, lines 28-35. Grollier's disclosure, furthermore, clarifies that only the anionic polymer is essential: "It is also possible, according to the invention, to use amphoteric polymers in place of the true cationic polymers, the said amphoteric polymers performing the same function as the true cationic polymers when they are associated with the anionic polymers used according to the invention." *Id.* at col. 8, lines 38-43. Particularly pertinent to

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Applicants' invention, Grollier specifically explains that a hair dye would comprise a cationic polymer <u>and</u> an anionic polymer. *Id.* at col. 13, lines 44-51.

Applicants point out, furthermore, that there is nothing in either Grollier or Lim that would have suggested to a person of ordinary skill in the art that a cationic polymer, which is described as merely optional in Lim and as not critical in Grollier (unlike its anionic polymers), in conjunction with a 1-(4-aminophenyl)pyrrolidine compound as recited in, e.g., claim 1 would improve the dyeing efficiency of the composition. Indeed, the only benefit that might have been expected (and Applicants do not even concede this point) would have related to the conditioning capacity and not the dyeing efficiency of the composition. Moreover, based on the teachings of Lim and Grollier, an ordinarily skilled artisan would have only been motivated to create a composition containing the specific oxidation base precursor taught by Lim with the combination of anionic and cationic polymers taught by Grollier. Thus, a person of ordinary skill in the art would not have been motivated to select, out of context, only a cationic polymer from Grollier's composition, then combine that selection with the dye intermediates found in Lim.

As for the De La Mettrie reference, it teaches a composition containing an 2-electron oxidoreductase-type enzyme in the presence of a donor for that enzyme and an amine silicone. See U.S. Pat. No. 6,254,646 to De La Mettrie ("the '646 patent"), col. 2, line 65 - col. 3, line 9.² De La Mettrie's composition "lead[s] to more homogeneous, more intense and more chromatic colorations without giving rise to any significant

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² The '646 patent issued from an application based on PCT/FR98/02027, whose publication the Examiner cited (i.e., WO 99/17722). Accordingly, the '646 patent's written description is the English equivalent of De La Mettrie.

degradation." *Id.* at col. 3, lines 4-6. This reference thus relates to "the drawback of causing appreciable degradation of fibres, as well as considerable bleaching of keratin fibres" when using hydrogen peroxide in dyeing keratin fibers. *Id.* at col. 1, lines 42-47. Applicants initially note that the problem solved by this reference is totally different than that solved by Applicants' claimed compositions. And, as noted previously, this problem is totally different from the problems solved by either Lim or Grollier.

Much like the fundamental pairing of anionic polymer with cationic polymer in Gollier's composition, the pairing of a particular enzyme with an aminosilicone in De La Mettrie's composition effectively resolves then-existing technical problems. Indeed, it is the specific combination of the particular enzyme and the aminosilicone that yields beneficial properties. See '626 patent, col. 2, line 65 - col. 3, line 9. Importantly, De La Mettrie discloses no deficiencies in the fundamental pairing of a particular enzyme with an aminosilicone that would suggest further combination. A person of ordinary skill in the art, therefore, would not have been motivated to select only one ingredient of De La Mettrie's composition and then combine such a selection with components of compositions found in separate references, such as a dye from Lim and a polymer from Grollier. The reference as a whole thus does not suggest selection of individual compounds for use in a wholly different compositions. See M.P.E.P § 2141.02.

Taken either individually or together, therefore, not one of Lim, Grollier, or De La Mettrie teaches or even remotely suggests a motivation to combine their teachings, particularly to combine selected teachings taken out of context of each patent as a whole. Furthermore, the Examiner has provided no evidence to support the

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combination, let alone the "clear and particular" evidence the law requires. *See Dembiczak*, 175 F.3d at 999.

C. The Examiner Has Not Shown A Reasonable Expectation Of Success

In addition to showing a motivation to combine the asserted references, the Examiner must show why a person of ordinary skill in the art would have had a reasonable expectation of success when combining the references. See, e.g., M.P.E.P. § 2143.02. In *In re Dow Chem. Co.*, 837 F.2d 469 (Fed. Cir. 1988), the Federal Circuit made it clear that obviousness is not based on an "obvious to try" or "obvious to experiment" standard. In reversing a determination of obviousness, the Court stated that the prior art must provide some teaching that one of ordinary skill in the art would have a reasonable expectation of success in combining the references. Id. at 471-73. The Court's instruction is even more important in the art of hair dyes, which is notoriously unpredictable. See, e.g., Zviak, THE SCIENCE OF HAIR CARE, at 271-272 (Charles Zviak ed., 1986) ("any varying element can cause a major change"). Here, the Examiner has failed to point to any reasonable expectation of success. And, in particular, as Applicants' specification makes clear: "By combining at least one (as used herein, "at least one" means one or more and thus includes mixtures and combinations) oxidation base chosen from 1-(4-aminophenyl)pyrrolidines and acid addition salts thereof with at least one cationic polymer, however, the inventors have just now discovered that it is possible to obtain oxidation dyes capable of producing shades of colors that may have at least one of the following properties: shades that are varied, chromatic, intense, aesthetic, not very selective, and/or that exhibit good resistance to the various attacks to which the fibers may be subjected." Specification at

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2 (emphasis added). Thus, as explained above, there would be no reasonable expectation of successfully producing a <u>hair dye</u> composition based on selected portions of Grollier's disclosure, which relates to a <u>conditioning</u> composition.

V. CONCLUSION

In view of the foregoing remarks, the rejection of the claims under 35 U.S.C. § 103(a) is in error and should be withdrawn. Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

By:

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: March 3, 2003

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Attorney Docket Number: 05725.0881

APPENDIX TO AMENDMENT OF MARCH 3, 2003

Version with Markings to Show Changes Made

Amendments to the Claims

1. A composition for oxidation dyeing keratinous fibers comprising, in a medium suitable for dyeing:

[(iii)] (i) at least one oxidation dye precursor chosen from 1-(4-aminophenyl)pyrrolidine of formula (I) and acid addition salts thereof:

$$R_3$$
 R_2
 R_1
 R_1
 R_1

wherein:

- R₁ is chosen from a hydrogen atom, C₁-C₆ alkyl groups, C₁-C₅ monohydroxyalkyl groups, and C₂-C₅ polyhydroxyalkyl groups,
- R₂ is chosen from a hydrogen atom, a –CONH₂ group, C₁-C₅ monohydroxyalkyl groups, and C₂-C₅ polyhydroxyalkyl groups, and
- R₃ is chosen from a hydrogen atom, and a hydrogen group, and
- (ii) at least one cationic polymer chosen from:

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(1) homopolymers and copolymers comprising, as a constituent of the chain, at least one unit chosen from units formula (II):

wherein:

- k and t, which are identical or different, are each chosen from 0 and 1, provided that the sum of k + t is equal to 1;

 R_4 and R_5 , which are identical or different, denote an alkyl group having from 1 to 22 carbon atoms, a (C_1-C_5) hydroxyalkyl group, a (C_1-C_4) amidoalkyl group, or R_4 and R_5 denote, together with the nitrogen atom to which they are attached, a piperidinyl or morpholinyl group;

 R_6 denotes a hydrogen atom or a methyl radical;

- X is an anion;
- -(2) the quaternary diammonium polymers containing repeat units of the following formula (III):

$$\begin{bmatrix}
R_{7} & R_{9} \\
 & | & | & | \\
 & N_{1} - A_{1} - N_{1} - B_{1} - | \\
 & | & | & | \\
 & R_{8} & R_{10} & 2X^{-}
\end{bmatrix}$$
(III)

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in which:

R₇, R₈, R₉ and R₁₀, which are identical or different, represent aliphatic, alicyclic or arylaliphatic

radicals containing from 1 to 20 carbon atoms or lower hydroxyalkylaliphatic radicals, or else R_7 , R_8 , R_9 and R_{10} , together or separately, form, with the nitrogen atoms to which they are attached, heterocyclic rings optionally containing a second heteroatom other than nitrogen,

or else R_7 , R_8 , R_9 and R_{10} represent a linear or branched C_1 - C_6 alkyl radical substituted by a nitrile, ester, acyl, amide or $-CO-O-R_{11}-D$ or $-CO-NH-R_{11}-D$ group in which R_{11} is an alkylene and D a quaternary ammonium group;

A₁ and B₁ represent polymethylene groups containing from 2 to 20 carbon atoms which are linear or branched, saturated or unsaturated, and which may contain, bonded to or inserted into the main chain, one or more aromatic rings, or one or more oxygen or sulphur atoms or sulphoxide, sulphone, disulphide, amino, alkylamino, hydroxyl, quaternary ammonium, ureido, amide or ester groups, and

X is an anion;

A₁, R₇ and R₉ may form, with the two nitrogen atoms to which they are attached, a piperazine ring; in addition if A₁ denotes a saturated or unsaturated, linear or branched alkylene or hydroxyalkylene radical, B₁ may also denote a group –(CH₂)n-CO-D-OC-(CH₂)n- in which n is between 1 and 100 and preferably between 1 and 50, and D denotes:

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a) a glycol residue of formula: -O-Z-O-, where Z denotes a linear or branched hydrocarbon radical or a group corresponding to one of the following formulae:

where x and y denote an integer from 1 to 4, representing a defined and unique degree of polymerization or any number from 1 to 4 representing a mean degree of polymerization;

- b) a disecondary diamine residue such as a piperazine derivative;
- c) a diprimary diamine residue of formula: -NH-Y-NH-, where Y denotes a linear or branched hydrocarbon radical or else the divalent radical

- d) a ureylene group of formula: -NH-CO-NH-;
- -(3) the quaternary diammonium polymers consisting of units of the following formula (IV):

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p denotes an integer varying from 1 to 6,

D is zero or represents a group $-(CH_2)_r$ -CO- in which r denotes a number equal to 4 or to 7, and

X is an anion;

-(4) the amine-containing silicones.

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